K002981 p. 1/2

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

APR - 9 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY:
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

CONTACT:
Ruth Ann Wood
Senior Regulatory Affairs Associate
Telephone: 513/337-3468
FAX: 513/337-7134

DATE PREPARED:
September 22, 2000

NAME OF THE DEVICE:
UltraCision® Harmonic Scalpel®
Classification: LFL

PREDICATE DEVICES:
ArthoCare Electrosurgical System
UltraCision Harmonic Scalpel LaparoSonic Shears

DEVICE DESCRIPTION:
The UltraCision Harmonic Scalpel is an ultrasonic surgical instrument for the cutting and coagulation of soft tissues. The device system has three essential parts: the generator/ footswitch, the hand piece and the instruments which are available in various lengths shapes and types.

INTENDED USE:
The UltraCision Harmonic Scalpel is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.

TECHNOLOGICAL CHARACTERIZATION:

The UltraCision Harmonic Scalpel is a medical device that uses ultrasonic energy to cause mechanical vibrations to cut and coagulate soft tissues.

PERFORMANCE DATA:

All previously submitted bench testing and animal studies demonstrated satisfactory performance in cutting and coagulation. Clinical information demonstrates satisfactory performance for the urologic indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Ms. Ruth Ann Wood
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K002981
Trade/Device Name: UltraCision® Harmonic Scalpel® Shears
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI and LFL
Dated: January 16, 2001
Received: January 17, 2001

Dear Ms. Wood:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K002981

DEVICE NAME: UltraCision® Harmonic Scalpel® Shears

INDICATIONS FOR USE:

The UltraCision Harmonic Scalpel instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter-Use
(Optional Fromat)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K002981